(b) whether there is any provision in Schedule-Y which provides compensation or insurance for the clinical trial patients or their families?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMDOSS): (a) and (b) The amended Schedule Y of the Drugs and Cosmetics Act prescribes for submission of adequate safety data for regulatory review, before permission is granted to conduct clinical trials.

Permission to conduct clinical trials for molecules invented outside India is granted only when the same trial is being concurrently conducted in other countries as well.

The amended Schedule Y mandates that Ethics Committees review "Insurance Policy/Compensation for participation and for serious adverse events occurring during the study participation."

The informed consent checklist under Schedule Y also prescribes that the patient should be informed by clinician (Investigator) about "Compensation and/or treatment (s) available to the Subject in the event of a trial-related injury."

According to India Good Clinical Practices (GCP) Guidelines, which must be complied with as per Schedule Y, the sponsor is responsible to indemnify and obtain insurance to cover the cost of treatment in case of any study related harm to patients, and also to provide compensation as prescribed by the laws of the land.

**NRHM in Punjab**

1275. SHRIVARINDER SINGH BAJWA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the National Rural Health Mission is functioning in Punjab;

(b) if so, the details thereof, location-wise; and

(c) the incentives/grants/aids given to the Mission during the last three years, year-wise?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMDOSS): (a) and (b) The National Rural Health Mission (NRHM) is functioning in the state of Punjab. The Mission was launched on 12th April 2005. The first year of Mission is the preparatory phase during which the institutional mechanisms for the implementation of the Mission have been laid down.

The departments of Health & Family Welfare have been merged for better coordination of the various activities. The state has also set up the basic institutional framework of the Mission including the State & District Health Missions. The state has also merged the various societies under different programmes. All Rogi Kalyan Samiti at district level and CHCs level have been set up.

(c) The grants given to the states of Punjab for the Mission are as follows:

| SI. No. | Programme | Funds released (Rs. in Crore) |
|---|---|---|
| 1. | RCH Flexipool Funds (including RCH-PIP, JSY etc.) | Rs. 17.42 |
| 2. | Upgradation of CHCs to IPHS | Rs. 6.80 |
| 3. | Untied Fund to SCs @Rs, 10,000 per 3CP.A. | Rs. 2.85 |
| 4. | Other F.W. programmes | Rs. 44.57 |
| 5. | Health Schemes | Rs. 2.22 |
| | TOTAL | Rs. 73.86 |

**Combo Vaccine**

1276. SHRI KARNENDU BHATTACHARJEE: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that India soon will have a Combo Vaccine;

(b) whether it is also a fact that this vaccine can be given against 4-5 diseases; and

(c) if so, the name of those diseases which are covered by this single dose?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAMDOSS): (a) to (c) Combination vaccines have been in use for over 50 years and India has been using combination vaccines in the national immunization programme. Some of the commonly used combination vaccines in Universal Immunization Programme (UIP) are Diphtheria Pertussis Tetanus (DPT), Diphtheria Tetanus (DT), Oral Polio Vaccine (OPV).